K000249 12/11/00

510(k) Summary of Safety and Effectiveness

Submitter: Schaefer Water Center
Hwy 61 - 67
1555 Commercial Boulevard
Herculaneum, MO 63048

Phone: (314) 931-2268

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Date Prepared: January 20, 2000

Contact Person: Michael Schaefer, P.E.

Device Names:

1) Trade name: Schaefer Water Centers Hemodialysis Water Purification System

2) Common name: Reverse Osmosis system with pretreatment and product water distribution components

3) Classification name: Water purification system for hemodialysis (21 CFR 876.5665)

Predicate Device: Marcor Water Purification System for Hemodialysis
#K945559

Device Description

The water purification system and its pretreatment and product water distribution components are designed to remove organic, inorganic, and microbiological contaminants from the water supplied to dialysis clinics and used to prepare dialysate solutions for hemodialysis. The system includes pretreatment components, reverse osmosis, and product water components.

Pretreatment components include a booster pump, temperature blending valve, particulate filtration, water softener, and granular activated carbon filtration. The purpose of the pretreatment components is to condition the water feeding the reverse osmosis unit. The booster pump is used to assure adequate feedwater pressure. The temperature blending valve maintains the incoming water temperature at an optimal level for the reverse osmosis membranes. Particulate filtration is accomplished with multi-media or cartridge sediment filters to protect the pretreatment equipment and the reverse osmosis

510(k) Summary of Safety and Effectiveness

Device Description (continued):

membranes. The water softener removes hardness in the form of calcium and magnesium to prevent the precipitation of salts on the membranes and to assure the final water quality of the permeate. The feedwater is then filtered through granular activated carbon filters to remove chlorine, chloramine, and organics.

The water then enters the reverse osmosis machine. The process of reverse osmosis, a type of crossflow membrane filtration, separates the incoming water into permeate and concentrate streams. A high pressure pump forces water into the pressure vessels housing the reverse osmosis membranes. The molecular cut-off weight of the membrane allows the passage of a filtered permeate stream to pass through the membrane. The membrane is designed to reject greater than 99 percent of bacteria, pyrogens, and particles, and 95 to 98 percent of the total dissolved solids. Deionization tanks may be used after reverse osmosis if required to assure compliance with ANSI/AAMI RD5-1996. The permeate may then be passed through an ultraviolet water sterilizer to further limit bacterial growth. A submicron filter is placed after the ultraviolet water sterilizer to remove endotoxin and microorganisms. The product water distribution components may include a storage tank repressurization pumps.

Intended Use

The Schaefer Water Centers' Water Purification System for Hemodialysis and its pretreatment and product water distribution components are intended for use with a hemodialysis system to remove organic and inorganic substances from water used to dilute dialysate concentrate to form dialysate and produce purified water for other purposes such as dialyzer reprocessing and equipment disinfection and rinsing.

Predicate Device

The Schaefer Water Centers' Water Purification System for Hemodialysis and its pretreatment and product water distribution components are substantially equivalent to the Marcor Water Purification System for Hemodialysis. Both systems use a reverse osmosis technology to purify water for use in hemodialysis applications and both systems use a reverse osmosis machine with 510(k) marketing clearance from FDA.

Non-clinical Performance Data

The Schaefer Water Centers' Water Purification System for Hemodialysis produces product water in compliance with the voluntary standard issued by the American National Standard Institute and the Association for the Advancement of Medical Instrumentation: ANSI / AAMI RD5-1996.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2000

Mr. Michael J. Schaefer, P.E.
Schaefer Water Center
Highway 61-67
1555 Commercial Boulevard
HERCULANEUM MO 63048

Re: K000249
Schaefer Water Center Hemodialysis
Water Purification System, HWPS-100
Dated: November 11, 2000
Received: November 13, 2000
Regulatory Class: II
21 CFR §876.5665/Procode: 78 FIP

Dear Mr. Schaefer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

Indications for Use Statement

510(k) Number: K000249

Device Name: Schaefer Water Centers' Water Purification System for Hemodialysis
(Trade Name) (Classification Name)

Indications for Use:

The Schaefer Water Centers' Water Purification System for Hemodialysis and its pretreatment and product water distribution components are intended for use with a hemodialysis system to remove organic and inorganic substances from water used to dilute dialysate concentrate to form dialysate and produce purified water for other purposes such as dialyzer reprocessing and equipment disinfection and rinsing.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K000249

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